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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,994	11/20/2001	Qiang Liu	8325-0011.20	1661

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EXAMINER
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CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,994

Applicant(s)

LIU, QIANG

Examiner

Karen Cochrane Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 2-7, 9-18, 20-22 and 24-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 8, 19 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2-1449s.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Applicant's election with traverse of a zinc finger protein comprising F1 sequence DRSNLTR, F2 sequence TSGHLR, and F3 sequence RSDHLR in the paper filed January 16, 2004 is acknowledged. The traversal is on the ground(s) that the Office has improperly refused to examine as a whole that which they regard as their invention and that Applicants' claimed invention clearly necessitates the recitation of multiple sequences inasmuch as it is drawn to zinc finger proteins (or polynucleotides encoding these proteins) that recognize a target site of the form GNNGNNGNN. Applicants also state that, in fact, all claimed amino acid sequences have the same structure (three-fingered, non-naturally occurring zinc finger protein in which each zinc finger comprises a sequence of seven-amino acid residues involved in binding to DNA), as described for example on page 9, lines 4-6, page 15, lines 5-7 and page 16, line 28 through page 18, line 5. Moreover, all claimed amino acid sequences have the same function (DNA binding), as described for example on page 11, lines 16- 18, on page 14, line 10 and on page 15, lines 7-9. Similarly, all claimed polynucleotides have the same structure (sequences that encode a three-fingered, non-naturally occurring zinc finger protein in which each zinc finger comprises a sequence of seven-amino acid residues involved in binding to DNA) and same function (encoding a zinc finger protein that binds DNA). Thus, Applicants submit that the Restriction Requirement cannot be sustained as between the claims of Groups 1-45 (claims 1-46) or between the claims of Groups 46-90 (claims 47-49). The record establishes that the amino acid sequences should be examined together and that the polynucleotide sequences should also be examined together since, for both the claimed amino acid sequences and the claimed polynucleotides, common structure and function are present.

Applicants also urge that it is untenable to separate the protein from the encoding DAN because it is well known that peptide synthesis techniques are not routinely capable of generating oligopeptides of this length that are readily purified or that are known to form functional tertiary structures. See, e.g., Gelinsky et al. (2002) Eur. J. Inorg. Chem. 2458-2462 (copy

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attached hereto), in which the authors state that the maximum peptide length for which clean chromatographic separation can be obtained is 25-30 amino acid residues.

Applicants urge that, in fact, both the claimed polypeptides of Groups 1-45, and the polynucleotides of Group 46-90, can be used in the same method, namely modulation of gene expression, as taught throughout the specification.

Applicants also traverse on the grounds that it would not be unduly burdensome to search the allegedly distinct inventions together. In fact, for the reasons noted above, it is required that multiple sequences be searched together. A search for any combination of F1, F2 and F3 zinc fingers would necessarily reveal art relevant to each of the allegedly distinct inventions." It would, therefore, not be burdensome (and even save the Office time and resources) to examine the claims together. Because the subject matter of all pending claims is related in both structure and function, there is no burden (let alone a serious burden) on the Examiner in searching and examining them together. Applicants reiterate that the polypeptides of Groups 1-45 and encoded by Groups 46-90 all have the same structure (three fingered zinc finger proteins, where each finger comprises a septa-peptide sequence that binds to DNA) and the same functions (DNA binding). Again, examining the groups together would save the Office time and effort, as a search for one group would necessarily reveal art relevant to the other groups.

This is not found persuasive because the polypeptides sequences do not have like structure or like function. For example, in claim 1, F1 having QRSVLVR binds GAA, while F1 having RSDNLAR binds GAG. There is no similarity in the F1s, or the target sequence. Thus, Applicants' arguments that the zinc fingers have the same structure and function are not persuasive.

Applicants' arguments that the encoding DNA has common structure and function is flawed for the same reasons set forth for the polypeptides.

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Applicants' assertion that the polypeptides and polynucleotides can be used to modulate gene expression is simple, meaning, the polypeptide acts on the DNA to cause transcription, while the DNA may block it.

Regarding burden of examination, the 4 inch stack of sequence data generated by searching only the elected 3 sequences has been burdensome, amplified by the fact that each "hit" for F1 must be individually taken with each "hit" for F2, and so on, taking a day just to review the results from the sequence search. To search more sequences would surely be burdensome. Further, because no one sequence comprises all 3 fingers searched, each and every document found to contain these sequence must be visually assessed to determine if the sequences represent F1, F2, and F3 in the N- to C- terminal order. Thus, the search of the elected invention has been burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 8, 19, and 23 are under examination. Claims 2-7, 9-18, 19-22, and 24-49 have been withdrawn from further examination by the Examiner because these claims are drawn to non-elected inventions.

If Applicants continue to disagree with the restriction requirement and its finality, Applicants may wish to petition. In that petition, Applicants must state on the record that the sequences are *not patentably distinct*, one from the other.

MPEP 2434, dealing with nucleotide sequences rather than peptide sequences, states that:

Nucleotide sequences encoding the same protein are not considered to be independent and distinct and will continue to be examined together. In some exceptional cases, the complex nature of the claimed material may necessitate that the reasonable number of sequences to be selected be less than 10. In other cases, applicants may petition pursuant to

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37 CFR 1.181 for examination of additional nucleotide sequences by *providing evidence that the different nucleotide sequences do not cover independent and distinct inventions*. For examples of typical nucleotide sequence claims and additional information on the search and examination procedures, see the above cited O.G. Notice. See also MPEP § 803.04.

Applicants should also note (MPEP 809.02a) that:

Should applicant traverse on the ground that the zinc finger proteins are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Also, if the petition is granted, it will be the burden of Applicants to specifically point out where each specific sequence for F1, F2, and F3 sequence combination set forth in Claim 1 is taught in any priority document. The Examiner has determined the priority for the instantly elected combination; it is fair to shift this burden to Applicants if a petition is filed and granted because they have already requested priority to applications that do not comprise the elected invention.

**Priority is set to the filing date, November 20, 2001.** The elected invention wherein F1 sequence DRSNLTR, F2 sequence TSGHLSR, and F3 sequence RSDHLSR is found N- to C- terminal in a zinc finger protein is not found in:

09/535,088, filed March 23, 2000 or

09/716,637, filed November 20, 2000 or

60/146,615, filed July 30, 1999

60/146,595, filed July 30, 1999 or

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60/126,239, filed March 24, 1999 or

60/126,238, filed March 24, 1999.

Thus, reference to these applications for priority should be deleted from the file.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 8, 19, and 23 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 5 of copending Application No. 10/006,069. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 5 of '069 lists VOP 32-E having a F1 sequence DRSNLTR, F2 sequence TSGHLSR, and F3 sequence RSDHLSR. VOP 32-E binds to target 5' - GGG GGT GAC - 3', thus when S1 comprises GAC, F1 is sequence DRSNLTR, when S2 comprises GGT, F2 is sequence TSGHLSR, and when S3 is GGG, F3 is sequence RSDHLSR. See Table 3 of '069.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1, 8, 19, and 23 are provisionally rejected under the judicially created doctrine of double patenting over claim 1-4, 6-18, and 91-93 of copending Application No. 10/006,069. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: VOP 32-E

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites non-elected subject matter and therefore does not particularly point out and distinctly claim the subject matter which applicant regards as the elected invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this



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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21 (2) of such treaty in the English language.

Claims 1, 8, 19, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Rebar et al. (2002; WO 02/46412, filed December 6, 2001, the instant sequence found in priority application 09/846,033 filed April 30, 2001) The applied reference has 3 common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Rebar et al. disclose a variety of zinc finger proteins said to regulate VEGF expression. At page 103, Table 3, zinc finger protein (ZFP) designated VOP 32-E having a F1 sequence DRSNLTR, F2 sequence TSGHLRSR, and F3 sequence RSDHLRSR. VOP 32-E binds to target 5' - GGG GGT GAC - 3', thus when S1 comprises GAC, F1 is sequence DRSNLTR, when S2 comprises GGT, F2 is sequence TSGHLRSR, and when S3 is GGG, F3 is sequence RSDHLRSR.

WO 02/46412 is a very large application. Therefore, only pertinent pages to this rejection are being sent: Front page and pages 101-107. Because the inventors overlap, it is assumed that Applicants have a copy of the WO document.

Claims 1, 8, 19, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Rebar et al. (US 2003/0021776, published January 30, 2003, from SN 10/006,069, priority for elected invention in 09/846,033, filed April 20, 2001)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132

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that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Rebar et al. disclose a variety of zinc finger proteins said to regulate VEGF expression. In Table 3, zinc finger protein (ZFP) designated VOP 32-E having a F1 sequence DRSNLTR, F2 sequence TSGHLSR, and F3 sequence RSDHLSR. VOP 32-E binds to target 5' - GGG GGT GAC - 3', thus when S1 comprises GAC, F1 is sequence DRSNLTR, when S2 comprises GGT, F2 is sequence TSGHLSR, and when S3 is GGG, F3 is sequence RSDHLSR. See Claim 5 for the specific claiming of VOP 32-E.

US 2003/0021776, published January 30, 2003, from SN 10/006,069 is a very large application. Therefore, only pertinent pages of this application are being sent: Front page, Tables 3 and 4, and the claims. Because the inventors overlap, it is assumed that Applicants have a copy of this document.

No Claims are allowed.

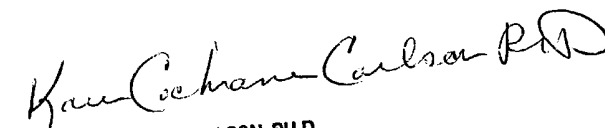
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER